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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,774	12/15/1999	LILY CHAN	1781-180P	4250

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EXAMINER
SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/461,774	CHAN ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17July2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' Response to Office Action, received 17July 2001, paper#13, is acknowledged. Claims 1, 2, 3, 4, 5, 6, 7, 8, and 9 have been amended. Claims 10-26 have been canceled.

2. Claims 1-9 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claims 8 and 9 under 35 U.S.C. 112, second paragraph, indefiniteness, for sequence identifiers, is withdrawn in light of the claim amendments.

Rejections Maintained

4. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, indefiniteness, for "substantially", is maintained for reasons of record.

Applicants argue that one skilled in the art would have no difficulty in determining whether a particular polypeptide was substantially not immunointeractive with human sera in the sense of the present claims. In support of applicants' argument, they cite: 1) the specification page 22, line 10 through page 24, line 29; 2) Example 8, pages 34-36; 3) Appendix; and 4) a copy of their own article.

The examiner has considered applicants arguments, but does not find it persuasive. While the supporting documentation does indicate varying levels of immunointeractivity of polypeptides with sera, the instant claims remain indefinite. Neither the instant specification nor the instant claims indicate any or which threshold levels distinguish immunointeractivity as being "substantial" over any other levels.

5. The rejection of claims 1-7 under 35 U.S.C. 102(b) as being anticipated by Thybo et al (*Tubercle and Lung Disease*, 76:149-155, 1995) is maintained.

Applicants argue that Thybo's study controls titers, i.e., 0.70, does not meet the present claims' requirement that the polypeptide is substantially not immunointeractive with sera from a human, animal, or avian species not prior exposed to said species of *Mycobacteium*.

The examiner has considered applicants' argument, but does not find it persuasive because of the indefiniteness of the term "substantially" immunointeractive or not immunointeractive discussed *supra*. Without any limitation on what constitute "substantial immunointeractivity" or "substantial nonimmunointeractivity", the instantly cited reference does meet all of the limitations of the instant claims. Thus, a control value of 0.70 **is** substantially nonimmunointeractive compared to 1.15.

New Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides encoded by the specified nucleotide sequences, does not reasonably provide enablement for polypeptides encoded by nucleotide sequences having

≥60% similarity or which hybridiz to any one of said sequences under low stringency conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim is drawn to any polypeptide which is encoded by a sequence having ≥60% similarity to either SEQ ID NO:1, 3, 5, 7, or 9. However, there is no restriction on how the sequence similarity effects the actual nucleotide sequence. For example, a sequence which is ≥60% similar to SEQ ID NO:1, which is 1617 nucleotides in length, may as one of the embodiments be different at every third nucleotide. This would shift the encoding sequence resulting in a totally different peptide from that which is encoding by SEQ ID NO:1. The instant specification does not contain sufficient support for such peptides, nor do the claims recite any limitation on the peptide such as retaining the same amino sequence or activity of the polypeptide encoded by SEQ ID NO:1. In identical fashion, nucleotides sequences which are ≥60% similar to SEQ ID NO:3, 5, 7, or 9 would also encode polypeptides which may not have any similarity to the polypeptides encoded by SEQ ID NO:3, 5, 7, or 9.

The claim is drawn to any polypeptide encoded by a nucleotide sequence capable of hybridizing to either SEQ ID NO:1, 3, 5, 7, or 9, under low stringency conditions. Because the conditions are low stringency, this results in any nucleotide sequence fulfilling the limitation even if it only hybridizes via 10-100 nucleotides. Thus, the identity of these nucleotides is unknown and the resulting polypeptides are likewise unknown, with unknown activity. The instant specification does not provide sufficient guidance/examples for the scope of the claim.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polypeptides SEQ ID NO:2, 4, 6, 8 and 10, does not reasonably

provide enablement for polypeptides which only have ≥60% similarity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim is drawn to any polypeptide which has ≥60% similarity in sequence with SEQ ID NO:2, 4, 6, 8, or 10. However, there is no recitation that these polypeptides exhibit the same activity or any activity in common with that of SEQ ID NO:2, 4, 6, 8, or 10.

The specification teaches that polypeptides with the sequences SEQ ID NO:2, 4, 6, 8, or 10 can be utilized in assays to distinguish between individuals who have been exposed to *Mycobacterium* and individuals who have not previously been exposed to *Mycobacterium*. However, the specification does not teach nor provide sufficient guidance for the scope of the instant claims, i.e., that all polypeptides which differ from SEQ ID NO:2, 4, 6, 8, or 10 by 1-40% no matter how that difference is exhibited in sequence retain the critical function of the parent sequences.

Conclusion

9. Claims 1-9 are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 17, 2003